Remuneration Between Related Entities In Light of Advisory Opinion No. 00-6

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Since 1991, the Office of Inspector General for the U.S. Department of Health and Human Services ("OIG") has taken conflicting positions in respect of how remuneration between related entities would be treated for purposes of the federal anti-kickback law, 42 U.S.C. § 1320-7b(b). On September 29, 2000, the OIG issued Advisory Opinion No. 00-6. Although this advisory opinion did not directly analyze remuneration between wholly owned or controlled entities, it did discuss such entities and thus arguably provides further insight into how related entities may be treated by the OIG for these purposes. Unfortunately, important questions remain unresolved. As a result, Advisory Opinion No. 00-6 provides only limited comfort in this area.

The Issue

The OIG has long taken the position that the "anti-kickback statute is not implicated when payments are transferred within a single corporate entity, for example from one division to another." 64 Fed. Reg. 63,518, 63,520 (Nov. 19, 1999), *citing* 56 Fed. Reg. 35, 952, 35, 983 (July 29, 1991). OIG's perspective with respect to similar payments between wholly owned or controlled entities, however, has changed over time.

When the OIG published the initial anti-kickback law safe harbor regulations in 1991, no safe harbor protection was included for transactions between wholly owned entities. OIG indicated, however, that it

was considering the adoption of an additional safe harbor protecting such payments:

> *Because the statute is implicated when payments are made from one entity to another even though the payments are made between entities with common ownership, we believe that safe harbor protection may be appropriate. However, we remain concerned about wholly owned shell entities that are established for a fraudulent purpose, for example, to help hide the identity of the owners or to shield assets. Nonetheless, we are considering a new safe harbor provision, that we anticipate publishing as a separate regulation, that would protect payments between wholly owned subsidiaries and other payments and other entities where exclusive ownership control is present and the practice is not otherwise abusive.*

56 Fed. Reg. at 35, 983. In November of 1999, when additional safe harbor regulations were adopted, OIG expressed reluctance to confirm its earlier position:

> *Comment: Several commentators urged the OIG… to provide specific safe harbor protection for payments between wholly owned entities, including parent entities and their wholly owned subsidiaries….*
>
> *Response: With respect to integrated delivery systems and payments between wholly owned entities, we… recognize that there are many lawful integrated delivery system arrangements and arrangements between wholly-owned entities in the marketplace today and that many of these arrangements may be beneficial to the Federal health care programs and its beneficiaries. We are concerned, however, that integrated delivery systems, including arrangements involving wholly-owned subsidiaries, may present opportunities for the payment of other improper financial incentives that result in overutilization of services and increased program costs and that may adversely affect quality of care and patient freedom of choice among providers… Accordingly, we do not anticipate providing safe harbor protection for integrated delivery systems and arrangements between wholly owned entities at this time. The advisory opinion process…is available for parties wishing to obtain OIG review of their particular integrated delivery or wholly owned arrangements.*

64 Fed. Reg. at 63,520. This statement does not reveal whether the OIG holds the broad view that such payments standing alone could implicate the anti-kickback law, or whether it holds a narrower view, that the law is implicated only when the payments are part of an indirect remuneration arrangement in which a third party that is a potential referral source is the ultimate recipient of the remuneration.

Advisory Opinion No. 00-6

Although Advisory Opinion No. 00-6 sheds some light on these issues, it does not fully illuminate them. Advisory Opinion No. 00-6 involved a hospital's proposed donation of its ownership interest in a medical office building to a state agency for use by a state medical school. The first insight into OIG's treatment of related entities is contained in the Opinion's Statement of Facts:

> *The State Agency is an agency of the State that oversees facilities, programs, and policies related to students, staff and faculty at institutions within the State Agency. University Y is the division of the State Agency that operates the Medical School in [city redacted] (the "City"), State. University Y's faculty practice plan is operated by the Faculty Practice Plan, a tax-exempt, nonprofit corporation.*
>
> *For purposes relevant to our analysis, we consider the State Agency, University Y, the Medical School, and the Faculty Practice Plan to be sufficiently related to be treated as a single entity. Therefore, for purposes of this Advisory Opinion, each of the foregoing, as well as all entities that are owned or controlled, in whole or in part, directly or indirectly, by any of the foregoing and related, directly or indirectly, to the operation of University Y (including, without limitation, [names redacted]) will be referred to collectively as "Entity Y".*

OIG Advisory Opinion No. 00-6 (Sept. 29, 2000) at 2. These two paragraphs reveal that under at least some circumstances entities can be "sufficiently related" to be treated as a single entity for anti-kickback purposes. The Opinion does not tell us how the Faculty Practice Plan is related to the State Agency, University and Medical School (the three of which appear truly to be one single legal entity). Presumably the relationship was not through ownership or absolute control; it seems reasonable to assume that would have been expressly stated had that been the case.

Related Parties

Even more striking was OIG's apparent willingness also to include as part of the single entity "all entities that are owned or controlled, in whole or in part, directly or indirectly, by any of the foregoing and related, directly or indirectly, to the operation" of the University. At first blush, the implications of such an approach for integrated delivery systems is far-reaching. Arguably any entities related by complete or partial ownership or control would be treated as a single legal entity and thus could transfer cash, other assets or services between them without implicating the anti-kickback statute.

Closer analysis reveals that Advisory Opinion No. 00-6 should not necessarily be read that expansively. Importantly, the hospital was not included in the group deemed to be a "single entity" for anti-kickback statute purposes. Although the OIG did recognize that the hospital was a "component[ ] of an academic medical center that historically [has] shared both a common mission in training physicians for, and providing quality medical care to, the people of the State and a common heritage [with the University] as [a] public institution[ ]," id at 5, the hospital apparently was not "sufficiently related" to the University, State Agency and Medical School for it to be treated with them and the Faculty Practice Plan as a single entity for anti-kickback statute purposes. Had that approach been taken, there would have been no issue and the Advisory Opinion could have stopped there.

Donation Implicates Statute

Of course, that is not how OIG saw it, concluding that the proposed donation implicated the anti-kickback law:

> *The OIG's position on the provision of free or below market value goods or services to referral sources is longstanding and clear: such arrangements are suspect. That is, the provision of free goods or services to any referral source may violate the anti-kickback statute if one purpose of the gift is to induce or reward referrals of Federal program business. In general, such arrangements give rise to an inference that one purpose of the gift is to induce referrals.*
>
> *The Proposed Donation is as straightforward as it is problematic: a substantial one-time donation by a hospital to a major referral source. (Since Entity Y employs, and is affiliated with, physicians who make referrals to Hospital X, Entity Y is a referral source for Hospital X). Accordingly, the Proposed Donation implicates the Federal anti-kickback statute.*

Sanctions Not Imposed

Id. In deciding not to impose sanctions in connection with the proposed donation, the OIG cited the relationship between the hospital and the other components of the academic medical center, recognizing that such relationships "are often organizationally and financially complex," as well as the initial financial terms on which the medical office building was built. More importantly, however, the OIG cited other attributes designed to "insulate physician judgment and income from pressure to refer" to the hospital, including:

- *Entity Y will not require or encourage Entity Y Physicians to refer patients to Hospital X or any other institution.*
- *Entity Y will not track referrals made by Entity Y Physicians to Hospital X or any other institution.*
- *Compensation paid to Entity Y Physicians (including, without limitation, base salaries paid for Teaching Physicians' clinical or academic services and variable bonuses paid for their clinical services) will not be related to the volume or value of referrals by such physicians to*

Hospital X or any other institution. Such compensation will be consistent with fair market value in arm's-length transactions.

- *On an annual basis, Entity Y will provide written notice of the limitations described in each of the there foregoing paragraphs to all Entity Y Physicians.*

Id. at 6. Thus, Advisory Opinion No. 00-6 leaves the question of remuneration between hospitals and related referral sources unresolved. Notwithstanding the extensive range of entities OIG treated as a single entity for anti-kickback statute purposes in this Opinion, the hospital involved was not one of them. The circumstances under which OIG would be willing to treat a hospital as part of a single entity where other portions of the combined entity make referrals to such hospitals are not known. This remains an issue of importance for many types of entities and organizations, and it would be appropriate for OIG to issue guidance in this area, in the form of safe harbors or otherwise, that could be relied upon by all.

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